STEP THERAPY POLICY

POLICY: Antifungals for Vulvovaginal Candidiasis Step Therapy Policy

- Brexafemme® (ibrexafungerp tablets – Scynexis)
- Diflucan® (fluconazole 150 mg tablets – Pfizer, generic)
- Miconazole vaginal suppository (100 mg, 200 mg, or 1,200 mg) [over-the-counter]
- Terconazole vaginal cream 0.4% (generic only)
- Terconazole vaginal cream 0.8% (generic only)
- Terconazole vaginal suppository 80 mg (generic only)

REVIEW DATE: 09/03/2025

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

The listed vaginal antifungals, oral fluconazole, and Brexafemme are indicated for the **treatment of vulvovaginal candidiasis**.[1-4] Brexafemme is also indicated to reduce the incidence of recurrent vulvovaginal candidiasis in adults and post-menarchal pediatric females.[1] Many of the vaginal antifungals are available as over-the-counter (OTC) products.[3,4]

Guidelines

Brexafemme is not addressed in the guidelines. The Centers for Disease Control and Prevention (CDC) Sexually Transmitted Infections Treatment Guidelines (2021) recommend an intravaginal product (e.g., miconazole, tioconazole) or oral fluconazole for the treatment of vulvovaginal candidiasis.[5] Treatment with an azole antifungal typically results in relief of symptoms and negative cultures in 80% to 90% of patients who complete treatment. There are no data to show superiority of one intravaginal product over another.[6] The efficacy of oral fluconazole and intravaginal antifungals is similar.

POLICY STATEMENT

This program has been developed to encourage the use of a Step 1 Product prior to the use of a Step 2 Product. If the Step Therapy rule is not met for a Step 2 Product at the point of service, coverage will be determined by the Step Therapy criteria below. All approvals are provided for 1 year in duration.

Step 1: generic fluconazole 150 mg tablets, miconazole vaginal suppository (over-the-counter kits that include miconazole vaginal suppository are also included), generic terconazole vaginal cream, generic terconazole vaginal suppository

Step 2: Brexafemme

***Antifungals for Vulvovaginal Candidiasis Step Therapy Policy* product(s) is(are) covered as medically necessary when the following step therapy criteria is(are) met. Any other exception is considered not medically necessary.**

CRITERIA

1. If the patient has tried one Step 1 Product, approve a Step 2 Product.

REFERENCES

1. Brexafemme® tablets [prescribing information]. Jersey City, NJ: Scynexis; November 2022.
2. Diflucan® tablets and powder for oral suspension [prescribing information]. New York, NY: Pfizer, February 2024.
3. Facts and Comparisons® Online. Wolters Kluwer Health, Inc.; 2025. Available at: http://fco.factsandcomparisons.com/lco/action/home. Accessed on September 2, 2025. Search terms: fluconazole, miconazole, terconazole.
4. Clinical Pharmacology [database online]. Elsevier Inc. © 2025. Available at https://www.clinicalkey.com/pharmacology/. Accessed on September 2, 2025. Search terms: fluconazole, miconazole, terconazole.
5. Workowski KA, Bachmann LH, Chan PA, et al. Sexually transmitted infections treatment guidelines 2021. *MMWR Recomm Rep*. 2021;70(4):1-187.
6. Pappas PG, Kauffman CA, Andes D, et al. Clinical practice guidelines for the management of candidiasis: 2016 update by the Infectious Diseases Society of America. *Clin Infect Dis*. 2016;62(4):e1-50.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	09/13/2023
Annual Revision	No criteria changes.	09/18/2024
Annual Revision	No criteria changes.	09/03/2025